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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,334	05/25/2005	Boris Linard	258087US0XPCT	8821

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

REDDIG, PETER J

ART UNIT	PAPER NUMBER
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1642

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	03/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 03/13/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/506,334

Applicant(s)

LINARD ET AL.

Examiner

Peter J. Reddig

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1642

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1 and 2 links inventions 1-2. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP '804.01.

Group 1, claim(s) 1-3, drawn to a medicinal product for antitumor immunotherapy in an HLA-B35 patient comprising ONE immunogenic peptide representing a T epitope presented by MHC I.

Art Unit: 1642

(Upon election of Group 1, applicant must further choose ONE polypeptide SEQ ID NO: from Claims 1-3: as each polypeptide represents an independent invention, not a species.)

Group 2, claim(s) 1 and 2, drawn to a medicinal product for antitumor immunotherapy in an HLA-B35 patient comprising MORE THAN ONE immunogenic peptide representing a T epitope presented by MHC I.

(Upon election of Group 2, applicant must further choose choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NO: from Claims 1-3: as each polypeptide represents an independent invention, not a species.)

Group 3, claim(s) 4, a multiepitope composition comprising at least two peptides of two different categories among the categories a), b), c), d) and e) as defined in claim 1

(Upon election of Group 3, applicant must further choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NOs from Claim 1 as each polypeptide represents an independent invention, not a species.)

Group 4, claim(s) 5, drawn to a multiepitope composition comprising at least one peptide from each of categories a), b), c), d) and e) as defined in claim 1.

(Upon election of Group 4, applicant must further choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NOs from Claim 1 as each polypeptide represents an independent invention, not a species.)

Groups 2-3 will be rejoined if the elected combination of polypeptides are commensurate in scope with the claims.

Group 5 claim(s) 6, drawn to the multiepitope composition as claimed in claim 4, consisting of a chimeric polypeptide comprising one or more copies of each of said peptides.

(Upon election of Group 5, applicant must further choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NOs from Claim 1 for the chimeric polypeptide, as each polypeptide represents an independent invention, not a species.)

Group 6, claim(s) 7, drawn to a polynucleotide encoding a chimeric polypeptide as claimed in claim 6.

(Upon election of Group 6, applicant must further choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NOs from Claim 1 for the chimeric polypeptide to be encoded by the vector, as each polypeptide represents an independent invention, not a species.)

Art Unit: 1642

Group 7, claim(s) 8, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell expresses a peptide as defined in claim 1.

(Upon election of Group 7, applicant must further choose ONE polypeptide SEQ ID NOs from Claim 1, as each polypeptide represents an independent invention, not a species.)

Group 8, claim(s) 9, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell is transfected with a polynucleotide as claimed in claim 7.

(Upon election of Group 8, applicant must further choose A SPECIFIC COMBINATION OF polypeptide SEQ ID NOs from Claim 1 for the chimeric polypeptide to be encoded by the vector, as each polypeptide represents an independent invention, not a species.)

Group 9, claim(s) 10, drawn a method for in vitro detection of CTLs directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with ONE peptide defined in claim 1; and detecting the presence or absence of a CTL directed against ONE of the antigens selected from the group consisting of Melan-A MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 9, applicant must further choose ONE polypeptide SEQ ID NOs from Claim 1 and the corresponding antigen to be detected, as each polypeptide represents an independent invention, not a species.)

Group 10, claim(s) 10, drawn a method for in vitro detection of CTLs directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with against MORE THAN ONE peptide defined in claim 1; and detecting the presence or absence of a CTL directed against MORE THAN ONE of the antigens selected from the group consisting of Melan-A MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 10, applicant must further choose A SPECIFIC COMBINATION ONE of polypeptide SEQ ID NOs from Claim 1 and the corresponding combination of antigens to be detected, as each polypeptide represents an independent invention, not a species.)

Group 11, claim(s) 11, drawn to the multiepitope composition as claimed in claim 5, consisting of a chimeric polypeptide comprising one or more copies of each of said peptides.

Art Unit: 1642

(Upon election of Group 11, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 1 as each polypeptide represents an independent invention, not a species.)

Group 12, claim(s) 12, drawn to a polynucleotide encoding a chimeric polypeptide as claimed in claim 11.

(Upon election of Group 12, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 1 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 13, claim(s) 13, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell is transfected with a polynucleotide as claimed in claim 12.

(Upon election of Group 13, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 1 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 14, claim(s) 14, drawn to a multiepitope composition comprising at least two peptides of two different categories among the categories a), b), c), d) and e) as defined in claim.

(Upon election of Group 14, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 15, claim(s) 15, drawn to the multiepitope composition as claimed in claim 14, consisting of a chimeric polypeptide comprising one or more copies of each of said peptides.

(Upon election of Group 15, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 16, claim(s) 16, drawn to a polynucleotide encoding a chimeric polypeptide as claimed in claim 15.

(Upon election of Group 16, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 17, claim(s) 17, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell is transfected with a polynucleotide as claimed in claim 16.

Art Unit: 1642

(Upon election of Group 17, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 18, claim(s) 18, drawn to a multi-epitope composition comprising at least one peptide from each of categories a), b), c), d) and e) as defined in claim 2.

(Upon election of Group 18, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 19, claim(s) 19, drawn to the multi-epitope composition as claimed in claim 18, consisting of a chimeric polypeptide comprising one or more copies of each of said peptides.

(Upon election of Group 19, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 20, claim(s) 20, drawn to a polynucleotide encoding a chimeric polypeptide as claimed in claim 19.

(Upon election of Group 20, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 21, claim(s) 21, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell is transfected with a polynucleotide as claimed in claim 20.

(Upon election of Group 21, applicant must further choose A SPECIFIC COMBINATION OF polypeptides SEQ ID NOs from Claim 2 as each polynucleotide encoding each polypeptide represents an independent invention, not a species.)

Group 22, claim(s) 22, drawn to an antigen-presenting cell expressing an MHC I HLA-B35 allele, wherein said cell expresses a peptide as defined in claim 2.

(Upon election of Group 22, applicant must further choose ONE polypeptide SEQ ID NO from Claim 2 as each polypeptide represents an independent invention, not a species.)

Art Unit: 1642

Group 23, claim(s) 23, drawn to a method for in vitro detection of CTLs directed against one or more of antigens selected from the group consisting of Melan-A, MAGE-A6, gp 100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with ONE peptide defined in claim 2; and detecting the presence or absence of a CTL directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 23, applicant must further choose ONE polypeptide SEQ ID NO from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 24, claim(s) 23, drawn to a method for in vitro detection of CTLs directed against one or more of antigens selected from the group consisting of Melan-A, MAGE-A6, gp 100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with MORE THAN ONE peptide defined in claim 2; and detecting the presence or absence of a CTL directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 24, applicant must further choose A SPECIFIC COMBINATION of polypeptide SEQ ID NOs from Claim 2 as each polypeptide represents an independent invention, not a species.)

Group 25, claim(s) 24, drawn to a method for in vitro detection of CTLs directed against one or more of antigens selected from the group consisting of Melan-A, MAGE-A6, gp 100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with ONE peptide defined in claim 3; and detecting the presence or absence of a CTL directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 25, applicant must further choose ONE polypeptide SEQ ID NO from Claim 3 as each polypeptide represents an independent invention, not a species.)

Group 26, claim(s) 24, drawn to a method for in vitro detection of CTLs directed against one or more of antigens selected from the group consisting of Melan-A, MAGE-A6, gp 100, tyrosinase and NY-ESO-1, comprising obtaining a biological sample from an HLA-B35 individual; contacting said biological sample with MORE THAN ONE peptide defined in claim 3; and detecting the presence or absence of a CTL directed against one or more of the antigens selected from the group consisting of Melan-A, MAGE-A6, gp100, tyrosinase and NY-ESO-1.

(Upon election of Group 26, applicant must further choose A SPECIFIC COMBINATION of polypeptide SEQ ID NOs from Claim 3 as each polypeptide represents an independent invention, not a species.)

Art Unit: 1642

1. It is noted for Applicant's convenience that the elections of polypeptide SEQ ID NO(s) for Groups 1-26 is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to a composition using multiple peptides which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention, *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEP 803.02.

2. Groups 1 through 26 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers and treatment of different diseases. Thus the claims are distinct as required by MPEP 806.05(c).

Art Unit: 1642

3. The technical feature linking Groups 1-26 appears to be immunogenic peptides representing a T epitope presented by MHC I. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-26 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-26 appears to be immunogenic peptides representing a T epitope presented by MHC I as described in claims 1-3.

However, teaches Thomson *et al.* (WO 01/090197, September 29, 2001, IDS) teach a peptide of claim 1 comprising the sequence EX₁AGIGILX₂ (SEQ ID NO: 1) in which X₁ represents A or P, and X₂ represents T or Y. Specifically, Thomson *et al.* teach MART which comprises the peptide EAAGIGILT (Figure 27, page 149/216) and a synthetic protein comprising the same sequence EAAGIGILT (Figure 27, page 179-180/216).

Therefore, the technical feature linking the inventions of Groups 1-25 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Art Unit: 1642

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Species Elections for Groups 5, 6, 8, 11, 12

A. Claims 6, 7, 9, 11, and 12 are generic to the following disclosed patentably distinct species of chimeric polypeptide:

- 1) chimeric polypeptide containing ONE copy of the elected peptide
- 2) chimeric polypeptide containing MORE THAN ONE copy of the elected peptide

If Applicants elect species A2, then applicants must elect a specific number of copies to be in the chimeric polypeptide.

Species Elections for Groups 9 and 10

A. Claim 10 is generic to one or more of 5 patentably distinct species of antigens. It is noted that the number of antigen combinations alone in Claim 10, 5 antigens as claimed, as calculated by factorial analysis is 120, that is $5! = 120$. Thus, the claim is drawn to 120 distinct species. Applicant is required to identify and elect ONE ANTIGEN OR A SPECIFIC, DEFINED COMBINATION THEREOF for examination wherein the antigens are:

- 1) Melan-A
- 2) MAGE-A6
- 3) gp 100
- 4) tyrosinase

Art Unit: 1642

5) NY-ESO-1

Species Elections for Group 15

A. Claim 15 is generic to the following disclosed patentably distinct species of chimeric polypeptide:

- 1) chimeric polypeptide containing ONE copy of the elected peptide
- 2) chimeric polypeptide containing MORE THAN ONE copy of the elected peptide

If Applicants elect species A2, then applicants must elect a specific number of copies to be in the chimeric polypeptide.

Species Elections for Group 19

A. Claim 19 is generic to the following disclosed patentably distinct species of chimeric polypeptide:

- 1) chimeric polypeptide containing ONE copy of the elected peptide
- 2) chimeric polypeptide containing MORE THAN ONE copy of the elected peptide

If Applicants elect species A2, then applicants must elect a specific number of copies to be in the chimeric polypeptide.

Species Elections for Groups 23, 24, 25, and 26

A. Claims 23 and 24 are generic to one or more of 5 patentably distinct species of antigens. It is noted that the number of antigen combinations alone in Claims 23 and 24, 5 antigens as claimed, as calculated by factorial analysis is 120, that is $5! = 120$. Thus, the claim is drawn to 120 distinct species. Applicant is required to identify and elect ONE ANTIGEN OR A SPECIFIC, DEFINED COMBINATION THEREOF for examination wherein the antigens are:

- 1) Melan-A

Art Unit: 1642

2) MAGE-A6

3) gp 100

4) tyrosinase

5) NY-ESO-1

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Further some of the species are related as combination and subcombination. Species in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

Art Unit: 1642

case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations is useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each species group above for the elected invention Group, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

Art Unit: 1642

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1642

Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

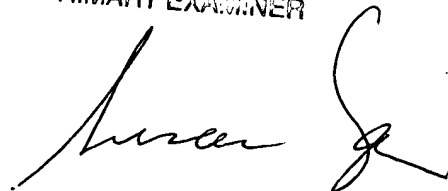
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan', followed by a large, stylized flourish or initial.

PJR